

Designation Run Report

Harper-Avilla, Stacy - Plaintiffs' Submission

Harper-Avilla, Stacy 04-11-2019

Plaintiffs Affirmative Designations 00:15:26

Plaintiff Counter Counters 00:00:13

Defense Completeness Counters 00:01:14

Total Time 00:16:52



SH03-Harper-Avilla, Stacy - Plaintiffs' Submission

Page/Line	Source	ID
16:17 - 16:19	Harper-Avilla, Stacy 04-11-2019 (00:00:05) 16:17 Would you just state your full name 16:18 for the record. 16:19 A. Stacy Harper-Avilla.	SH03.81
17:22 - 18:01	Harper-Avilla, Stacy 04-11-2019 (00:00:09) 17:22 Q. And you understand that today you 17:23 are providing testimony on behalf of the DEA? 17:24 A. Yes. 17:25 MR. O'CONNOR: I'm going to mark 18:1 Exhibit 1.	SH03.1
18:02 - 18:11	Harper-Avilla, Stacy 04-11-2019 (00:00:27) 18:2 (Deposition Exhibit 1 was marked for 18:3 identification.) 18:4 BY MR. O'CONNOR: 18:5 Q. This is a notice of deposition. 18:6 Have you ever seen this document 18:7 before? 18:8 A. Yes. 18:9 Q. And I'm going to ask you to turn to 18:10 Exhibit B, which is the letter from the U.S. 18:11 Department of Justice.	P-41927_1.1 SH03.2
18:12 - 18:20	Harper-Avilla, Stacy 04-11-2019 (00:00:29) 18:12 Have you ever seen this document 18:13 before? 18:14 A. Yes. 18:15 Q. Okay. And do you understand it to 18:16 be the letter authorizing testimony on certain 18:17 subjects on behalf of the DEA? 18:18 A. Yes. 18:19 Q. Let's go ahead and turn to Page 6 18:20 and I direct your attention to Topic 13.	P-41927_1.13.1 P-41927_1.14 SH03.3
18:21 - 19:09	Harper-Avilla, Stacy 04-11-2019 (00:00:44) 18:21 It says: "Topic 13. Your practices 18:22 and procedures related to the establishment of 18:23 opioid procurement quotas and opioid production 18:24 quotas for prescription opioids." 18:25 Are you authorized by the DEA to 19:1 testify regarding that topic today? 19:2 A. Yes. 19:3 Q. And I now direct your attention to:	P-41927_1.19.1 P-41927_1.19.2 SH03.4 P-41927_1.19.4

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19:4 "Topic 14, the basis for opioid procurement 19:5 quotas and opioid production quotas of 19:6 prescriptions from 1995 to 2018." 19:7 Are you authorized by the DEA to 19:8 provide testimony regarding that topic today? 19:9 A. Yes.		P-41927_1.19.5
19:10 - 19:18 Harper-Avilla, Stacy 04-11-2019 (00:00:17)		SH03.5
19:10 Q. Okay. 19:11 MR. CHANDLER: I do want to note for 19:12 the record that Ms. Avilla's authorization 19:13 extends insofar as the qualifications that are 19:14 also included in this letter. 19:15 MR. O'CONNOR: Understood. 19:16 BY MR. O'CONNOR: 19:17 Q. If you could turn to Page 9 of that 19:18 same document.		P-41927_1.22
19:19 - 20:15 Harper-Avilla, Stacy 04-11-2019 (00:01:00)		SH03.6
19:19 And look at Topic 3, which reads: 19:20 "DEA's establishment of quotas for the 19:21 production of opioids in the United States 19:22 including aggregate production quotas, 19:23 individual quotas and procurement quotas, the 19:24 disclosure of quota to registrants, 19:25 communications with registrants regarding quota 20:1 requests and the disposition of quota requests 20:2 and the relationship between quota, suspicious 20:3 orders, diversion and lawful medical, 20:4 scientific or industrial channels or use." 20:5 Did I read that correctly? 20:6 A. Yes. 20:7 Q. And are you authorized by DEA to 20:8 provide testimony on that topic today? 20:9 A. Yes. 20:10 Q. So when I ask a question, unless I 20:11 specifically indicate that I am asking for your 20:12 personal opinion, I am going to be asking for 20:13 the DEA's answer to that question. 20:14 Does that make sense? 20:15 A. Yes.		P-41927_1.22.1
21:18 - 23:09 Harper-Avilla, Stacy 04-11-2019 (00:01:44)		SH03.7

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Page/Line	Source	ID
21:18	Q. Ms. Avilla, what is your current	clear
21:19	role at DEA?	
21:20	A. I'm the section chief of United	
21:21	Nations Reporting and Quota Section.	
21:22	Q. And what do your responsibilities in	
21:23	that role include?	
21:24	A. The responsibilities are to manage	
21:25	the quotas for controlled substances in	
22:1	Schedules I and II, report back to the UN on	
22:2	the U.S. -- usage consumption of those	
22:3	substances as well as for setting the	
22:4	assessments and estimates for items in	
22:5	Schedules III through V, controlled substances	
22:6	in III through V.	
22:7	Q. How long have you been in that	
22:8	position?	
22:9	A. Since July of last year.	
22:10	Q. Before that, did you hold any	
22:11	position at DEA?	
22:12	A. Yes, I did.	
22:13	Q. What was that?	
22:14	A. I was the unit chief of the same	
22:15	section.	
22:16	Q. You were working with quotas in that	
22:17	role as well?	
22:18	A. Yes.	
22:19	Q. What was your position at DEA, if	
22:20	any, before that time?	
22:21	A. I don't understand the question.	
22:22	Q. Did you have a job at DEA before	
22:23	that role as unit chief?	
22:24	A. Yes.	
22:25	Q. What was that?	
23:1	A. Drug science specialist.	
23:2	Q. Okay. When you were a drug science	
23:3	specialist, did you have any involvement in	
23:4	quota issues?	
23:5	A. Yes.	
23:6	Q. Was that role your first at DEA?	
23:7	A. Yes.	

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	23:8 Q. And when did you start in that role?	
	23:9 A. 2008.	
23:10 - 23:16	Harper-Avilla, Stacy 04-11-2019 (00:00:14)	SH03.8
	23:10 Q. So am I correct that you joined the	
	23:11 Drug Enforcement Administration in 2008?	
	23:12 A. Correct.	
	23:13 Q. Okay. And since that time, your	
	23:14 work has included work on quota-related	
	23:15 matters?	
	23:16 A. Yes.	
49:02 - 49:04	Harper-Avilla, Stacy 04-11-2019 (00:00:07)	SH03.13
	49:2 Q. Okay.	
	49:3 MR. O'CONNOR: I'm going to mark	
	49:4 Exhibit 2.	P-41928_1.1
49:05 - 49:14	Harper-Avilla, Stacy 04-11-2019 (00:00:24)	SH03.14
	49:5 (Deposition Exhibit 2 was marked for	
	49:6 identification.)	
	49:7 BY MR. O'CONNOR:	
	49:8 Q. Do you recognize this document?	P-41928_1.1.1
	49:9 A. Yes.	
	49:10 Q. What is it?	
	49:11 A. It is a page from the C.F.R.	
	49:12 Q. Okay. Was this a portion of the	
	49:13 C.F.R. that you used in connection with your	
	49:14 role as unit chief and section chief?	
49:17 - 49:22	Harper-Avilla, Stacy 04-11-2019 (00:00:14)	SH03.15
	49:17 THE WITNESS: I don't understand the	
	49:18 question.	
	49:19 BY MR. O'CONNOR:	
	49:20 Q. Okay. When you were working on	
	49:21 quota issues, did you ever refer to this	
	49:22 regulation?	
49:24 - 50:24	Harper-Avilla, Stacy 04-11-2019 (00:01:24)	SH03.16
	49:24 THE WITNESS: Can I have the	
	49:25 question back.	
	50:1 BY MR. O'CONNOR:	
	50:2 Q. Sure. When you were working on	
	50:3 quota issues, did you ever refer to this	
	50:4 regulation?	
	50:5 A. When I was working on the aggregate	

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50:6 production quota, then this section that you 50:7 printed, yes.		
50:8 Q. And specifically, I would like to 50:9 talk about Section 1303.11(b), which says: "In 50:10 making this determination, the administrator 50:11 shall consider the following factors."	P-41928_1.1.2	
50:12 Do you see that?		
50:13 A. Yes.		
50:14 Q. Okay. And then it goes on to list 50:15 five items.		
50:16 The first is: "Total net disposal 50:17 of the class by all manufacturers during the 50:18 current and two preceding years."	P-41928_1.1.3	
50:19 Did DEA consider that factor when 50:20 setting the aggregate production quotas between 50:21 1995 and 2018?		
50:22 A. Yes.		
50:23 Q. And what does it mean to say the 50:24 "total net disposal of the class?"	P-41928_1.1.4	
50:25 - 51:12 Harper-Avilla, Stacy 04-11-2019 (00:01:00)		SH03.17
51:1 A. So total net disposal would be the 51:2 aggregate disposal disposition of all the 51:3 manufacturers, not counting their manufacturing 51:4 losses or their returns to other manufacturers.		
51:5 Q. Okay. Okay. No. 2 says: "Trends 51:6 in the national rate of net disposal of the 51:7 class."	P-41928_1.1.5	
51:8 What does that mean?		
51:9 A. Trends in national rate would be 51:10 changes in disposal rates.		
51:11 Q. How would DEA take into account 51:12 trends in the national rate of net disposal 51:13 when determining aggregate production quotas?		
51:13 - 52:24 Harper-Avilla, Stacy 04-11-2019 (00:02:21)		SH03.18
52:1 A. The main factor would be from FDA.		
52:2 Q. Okay. And in each year from 1995 to 52:3 2018, did DEA, in fact, consider the trends in 52:4 the national rate of net disposal of the class 52:5 when setting aggregate production quotas?		
52:6 A. Yes.		

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51:19 - 52:6	Q. No. 3 says: "The total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation." What does that mean? A. Total inventory would be the amount that the manufacturers have remaining after they have manufactured a substance but had not disposed of it. Q. Okay. And did the DEA take that into account each year between 1995 and 2018 when setting the aggregate production quota? A. Yes.	P-41928_1.1.6
52:7 - 53:17	Q. No. 4 says: "Projected demand for such class as indicated by procurement quotas requested pursuant to Section 1303.12." What does that mean? A. Projected demand would be the amount of material being requested through procurement quotas. Q. And did the DEA consider that factor each year in setting aggregate production quota? A. Yes.	P-41928_1.1.7
53:18 - 53:24	Q. No. 5 says: "Other factors affecting medical, scientific research and industrial needs in the United States and lawful export requirements as the administrator finds relevant." What other factors did DEA consider when setting the aggregate production quota?	P-41928_1.1.8
53:01 - 53:02	Harper-Avilla, Stacy 04-11-2019 (00:00:02)	SH03.19
53:04 - 53:07	Harper-Avilla, Stacy 04-11-2019 (00:00:14)	SH03.20
53:09 - 53:15	Q. So by way of example of oxycodone, what other factors contemplated by Subsection 5 did the DEA consider when setting aggregate production quota? Harper-Avilla, Stacy 04-11-2019 (00:00:29)	SH03.21

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	53:9 THE WITNESS: It would be the number 53:10 of manufacturers, their actual use and need for 53:11 the material, known diversion, known abuse. 53:12 BY MR. O'CONNOR: 53:13 Q. And were those factors you just 53:14 listed considered every year between 1995 and 53:15 2018?	
53:17 - 53:18	Harper-Avilla, Stacy 04-11-2019 (00:00:02)	SH03.22
	53:17 THE WITNESS: When there was data, 53:18 yes.	
116:11 - 116:15	Harper-Avilla, Stacy 04-11-2019 (00:00:19)	SH03.55 clear
	116:11 Q. But it's true that DEA understands 116:12 that ultimately, pharmacies may dispense to 116:13 patients across this country, an amount of the 116:14 controlled substance that is set by the 116:15 aggregate production quota, correct?	
116:18 - 116:20	Harper-Avilla, Stacy 04-11-2019 (00:00:06)	SH03.56
	116:18 THE WITNESS: A pharmacy may 116:19 dispense an amount needed for legitimate 116:20 patient need.	
118:18 - 118:21	Harper-Avilla, Stacy 04-11-2019 (00:00:13)	SH03.57
	118:18 Q. Well, in setting the annual 118:19 production quota, would you agree that DEA has 118:20 the ability to control how much of a 118:21 prescription opioid is available to the public?	
118:24 - 119:08	Harper-Avilla, Stacy 04-11-2019 (00:00:22)	SH03.58
	118:24 THE WITNESS: I would not. 118:25 BY MR. EPPICH: 119:1 Q. Why not? 119:2 A. Because there are many other factors 119:3 in between the number that is set and what goes 119:4 out to the public. 119:5 Q. What are those factors? 119:6 A. Manufacturing losses and yield, FDA 119:7 recalls, FDA changes in market practices, 119:8 manufacturers losing contracts, among others.	
139:15 - 139:20	Harper-Avilla, Stacy 04-11-2019 (00:00:18)	SH03.59
	139:15 Q. Is the responsibility for 139:16 manufacturers and distributors to monitor for 139:17 suspicious orders, stopping shipments of	

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139:25 - 140:11	<p>139:18 suspicious orders and inform the DEA, does that 139:19 responsibility go away because there is a quota 139:20 system in place by the DEA?</p> <p>Harper-Avilla, Stacy 04-11-2019 (00:00:26)</p> <p>139:25 THE WITNESS: So the quota system is 140:1 one portion of it, but it's incumbent upon the 140:2 manufacturers and distributors and all of the 140:3 participants within the quota system, within 140:4 the controlled substance system, to do their 140:5 part as per the regulations.</p> <p>140:6 BY MR. ELSNER:</p> <p>140:7 Q. Okay. So simply because there is a 140:8 quota system in place, that doesn't excuse 140:9 manufacturers and distributors from fulfilling 140:10 their other obligations under the Controlled 140:11 Substances Act; is that right?</p>	SH03.60
140:14 - 140:14	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:01)</p>	SH03.61
151:01 - 151:03	<p>140:14 THE WITNESS: True.</p> <p>Harper-Avilla, Stacy 04-11-2019 (00:00:07)</p> <p>151:1 Q. Okay. The quota system run by the 151:2 DEA is also national in scope; is that right?</p> <p>151:3 A. Correct.</p>	SH03.82
151:04 - 151:09	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:14)</p> <p>151:4 Q. Okay. It didn't -- it doesn't look 151:5 at -- the quota system for the DEA doesn't look 151:6 at how many pills a distributor like 151:7 AmerisourceBergen or Cardinal could distribute 151:8 to a particular pharmacy in a particular 151:9 community, does it?</p>	SH03.62
151:12 - 151:12	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:02)</p>	SH03.63
151:14 - 151:19	<p>151:12 THE WITNESS: It does not.</p> <p>Harper-Avilla, Stacy 04-11-2019 (00:00:17)</p> <p>151:14 Q. Okay. And the quota system, even if 151:15 you reduce the quota, it couldn't prevent a 151:16 distributor like McKesson from distributing 151:17 112,000 doses units of Hydrocodone products 151:18 into one pharmacy in West Virginia with a 151:19 population of 1500 people, could it?</p>	SH03.64
151:23 - 151:25	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:06)</p> <p>151:23 THE WITNESS: The quota system is</p>	SH03.65

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152:02 - 152:11	<p>151:24 national so it has no control over distributor 151:25 contracts.</p> <p>Harper-Avilla, Stacy 04-11-2019 (00:00:19)</p> <p>152:2 Q. And the DEA, through the quota 152:3 system, it doesn't analyze and approve 152:4 individual orders from pharmacies, to 152:5 manufacturers or to wholesale distributors, 152:6 does it?</p> <p>152:7 A. It does not.</p> <p>152:8 Q. Okay. And the quota system doesn't 152:9 authorize the number of pills that could be 152:10 distributed into Summit County or Cabell County 152:11 in West Virginia, does it?</p>	SH03.66
152:14 - 152:20	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:16)</p> <p>152:14 THE WITNESS: It does not.</p> <p>152:15 BY MR. ELSNER:</p> <p>152:16 Q. And it doesn't authorize the number 152:17 of pills that a distributor could send to any 152:18 city or county in the United States, does it?</p> <p>152:19 A. It does not. It is national. It is 152:20 not county, not city, not state-specific.</p>	SH03.67
177:03 - 177:07	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:12)</p> <p>177:3 Q. Ma'am, as you pointed out, the DEA 177:4 didn't just rely on the manufacturer's 177:5 information to set quota. The DEA also looked 177:6 at prescription data; is that true?</p> <p>177:7 A. Correct.</p>	SH03.68
177:09 - 177:20	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:43)</p> <p>177:9 BY MR. ELSNER:</p> <p>177:10 Q. And did that include data provided 177:11 by IMS and later equivalence of that company?</p> <p>177:12 A. Yes.</p> <p>177:13 Q. And would you agree with me that if 177:14 manufacturers and distributors of opioids had 177:15 misled doctors and the public about the health 177:16 benefits and the addictive nature of opioids 177:17 they were manufacturing and distributing 177:18 causing sales to rise, then the DEA's estimate 177:19 of the medical need could be above the actual 177:20 medical need in the United States?</p>	SH03.69

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177:25 - 177:25	Harper-Avilla, Stacy 04-11-2019 (00:00:01)	SH03.70
	177:25 THE WITNESS: Yes.	
186:05 - 186:09	Harper-Avilla, Stacy 04-11-2019 (00:00:12)	SH03.71
	186:5 Q. Okay. Now if the supply was limited	
	186:6 -- so I am done with the document now.	
	186:7 If the supply were limited, if you	
	186:8 decreased the quota, would that stop all	
	186:9 diversion?	
186:11 - 186:11	Harper-Avilla, Stacy 04-11-2019 (00:00:01)	SH03.72
	186:11 THE WITNESS: No.	
186:20 - 186:21	Harper-Avilla, Stacy 04-11-2019 (00:00:07)	SH03.73
	186:20 Q. It would simply mean that gross bulk	
	186:21 amount of a particular gross drug type would be	
186:22 - 186:22	Harper-Avilla, Stacy 04-11-2019 (00:00:01)	SH03.74
	186:22 less, correct?	
186:25 - 186:25	Harper-Avilla, Stacy 04-11-2019 (00:00:01)	SH03.75
	186:25 THE WITNESS: Correct.	
187:20 - 187:23	Harper-Avilla, Stacy 04-11-2019 (00:00:14)	SH03.76
	187:20 Q. And so if we reduce the size of the	
	187:21 quota simply reduces the pool of available	
	187:22 drugs, both to the licit and illicit users of	
	187:23 that drug, correct?	
188:03 - 188:07	Harper-Avilla, Stacy 04-11-2019 (00:00:07)	SH03.77
	188:3 THE WITNESS: It reduces the amount	
	188:4 of material available, period.	
	188:5 BY MR. ELSNER:	
	188:6 Q. Across the board?	
	188:7 A. Across the board.	
218:02 - 218:09	Harper-Avilla, Stacy 04-11-2019 (00:00:15)	SH03.78
	218:2 Q. Earlier in the deposition, you were	
	218:3 asked a question that -- during the years that	
	218:4 you approved the quota numbers, did you feel	
	218:5 that they reflected the medical need of the	
	218:6 United States?	
	218:7 Do you remember that line of	
	218:8 questioning?	
	218:9 A. Yes.	
218:14 - 218:17	Harper-Avilla, Stacy 04-11-2019 (00:00:14)	SH03.79
	218:14 Q. And you answered that you believed	
	218:15 that when you were approving quota allocations,	

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218:21 - 218:24	218:16 they were based on legitimate medical need. 218:17 Do you remember that testimony? Harper-Avilla, Stacy 04-11-2019 (00:00:09) 218:21 THE WITNESS: So when I approved 218:22 quota, it was for a legitimate medical need or 218:23 scientific or research purposes or export or 218:24 inventory.	SH03.80

Plaintiffs Affirmative Designations = 00:15:26

Plaintiff Counter Counters = 00:00:13

Defense Completeness Counters = 00:01:14

Total Time = 00:16:52

Documents Shown

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P-41928_1